

REMARKS

Claims 19 and 80-83 are pending. Claims 19 and 80-83 have been amended herein to more clearly define the invention. Support for the amendment to claim 19 can be found at, *e.g.*, page 65, lines 25-31. No new matter has been added by this amendment.

Rejection under 35 USC § 112, First Paragraph

Claims 19 and 80-83 have been rejected under 35 USC § 112, first paragraph, as containing new matter. The Examiner states that “there is no support in the specification for a nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 24 and further comprising the nucleotides of the 5’ untranslated region of SEQ ID NO: 23 or a variant.” Applicants traverse for the following reasons.

The as-filed specification discloses that the nucleic acid of SEQ ID NO: 23 is 1,014 nucleotides in length, has a 5’ untranslated region from nucleotides 1-54, a 3’ untranslated region from nucleotides 985-1014, and an open reading frame from nucleotides 55-984. *See, e.g.*, page 53, lines 8-17 and Table 49. The specification explicitly discloses that the open reading frame encodes for a 310 amino acid polypeptide of SEQ ID NO:24. *See, e.g.*, page 53, lines 8-17 and Table 50.

Moreover, Applicants contend that to one of ordinary skill in the art, the disclosure of the nucleic acid sequence of SEQ ID NO: 23 inherently discloses the translated polypeptide sequence of SEQ ID NO: 24. The specification also discloses variant nucleic acid molecules that differ from the nucleotide sequences shown in SEQ ID NO: 23 due to the degeneracy of the genetic code, and states that these nucleic acids thus encode the same NOVX protein as that encoded by the nucleotide sequence shown. *See, e.g.*, page 66, lines 22-29. Further, the specification discloses nucleic acid fragments, defined in the specification as sequences of at least 6 (contiguous) nucleic acids, which is a length sufficient to allow for specific hybridization in the case of nucleic acids and of at most some portion less than a full length sequence. *See, e.g.*, page 64, lines 12-15.

Thus, for the above-stated reasons, Applicants contend that claims 19 and 80-83 do not contain new matter. Applicants request that this rejection be withdrawn.

Rejection Under 35 USC § 112, Second Paragraph

Claim 19 has been rejected under 35 USC § 112, second paragraph, as being indefinite in the recitation of “or the complement of said nucleic acid sequence.” Applicants have herein amended claim 19 to recite the phrase “or the complement of said nucleic acid molecule” following “A method for determining the presence or amount of a nucleic acid molecule,” as suggested by the Examiner in the Office action. Therefore, this rejection has been overcome and should be withdrawn.

Rejection Under 35 USC § 102(e)

Claims 19 and 80-83 have been rejected under 35 USC § 102(e) as anticipated by WO 01/076121 (“Au-Young”). The Examiner states that “the present invention is drawn to a method for determining the presence or amount of a nucleic acid in a sample, a probe that binds to the nucleic acid sequence taught by Au-Young et al would also bind the nucleic acid of the preamble.” (See Office Action, page 4).

Applicants have amended claim 19 to recite, in part, “(b) introducing said sample to a probe that binds to said nucleic acid molecule or said complement, wherein said probe binds to at least nucleotides 45-56 of SEQ ID NO: 23 or the complement thereof...” This amendment is supported by the as-filed application at, e.g., page 65, lines 25-31, which discloses that a probe typically comprises a substantially purified oligonucleotide that typically comprises a region of nucleotide sequence that hybridizes under stringent conditions to at least about 12 or more consecutive sense strand nucleotide sequence of SEQ ID NO: 23, or an anti-sense strand nucleotide sequence of SEQ ID NO: 23, or of a naturally occurring mutant of SEQ ID NO: 23.

Applicants note that nucleotides 45-54 of SEQ ID NO: 23 are found in the 5' untranslated region (5'UTR). Because Au-Young does not teach or suggest a nucleic acid comprising nucleotides 45-54 of SEQ ID NO:23, a probe comprising the nucleic acid disclosed by Au-Young cannot bind to at least nucleotides 45-56 of SEQ ID NO: 23 or the complement thereof, as recited in amended claim 19. Thus, Au-Young does not anticipate claim 19, as amended herein. Moreover, claims 80-83, which each recite portions of the 5'UTR of SEQ ID NO: 23, which is

not taught or suggested by Au-Young, also are not anticipated by Au-Young. Therefore, Applicants contend that claims 19 and 80-83 are novel in view of this reference. Thus, this rejection should be withdrawn.

Objection Under 37 CFR § 1.75(c)

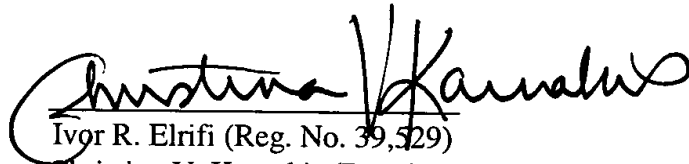
Claims 80-83 have been objected to under 37 CFR § 1.75(c) as being in improper dependent form for failing to limit the subject matter of claim 19. Applicants have amended claims 80-83 herein to more clearly define the invention. Specifically, claim 80 has been amended to recite that the nucleic acid molecule encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 24 and further comprises nucleotides 35-54 of SEQ ID NO:23 or a variant thereof. Since claim 19 requires that the nucleic acid molecule encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 24 and further comprises nucleotides 45-54 of SEQ ID NO:23 or a variant thereof, claim 80 requires an additional 10 nucleotides as compared to the claimed nucleic acid molecule of claim 19. Similarly, claim 81 requires an additional 20 nucleotides as compared to the claimed nucleic acid molecule of claim 19; claim 82 requires an additional 30 nucleotides as compared to the claimed nucleic acid molecule of claim 19; and claim 83 requires an additional 45 nucleotides as compared to the claimed nucleic acid molecule of claim 19. Thus, Applicants assert that claims 80-83 each further limit the subject matter of claim 19, as required by 37 CFR § 1.75(c). Therefore, this objection should be withdrawn.

CONCLUSION

Applicants submit that the Examiner's rejections have been overcome based on the enclosed amendments and remarks. Applicants therefore respectfully request that the pending claim be found allowable at this time. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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